

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Esteban Cvitkovich Confirmation No.: 9636  
Serial No.: 09/787,461 Group Art 1614  
Filed: March 2, 2001 Examiner: Phyllis G. Spivack  
For: Compositions and Uses of et743 for Treating Cancer

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

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2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
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- ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.
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- b. the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.
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- a. ☐ 37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);
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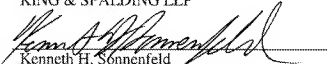
counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
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- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13566.105002.

Respectfully submitted,  
KING & SPALDING LLP

Dated: July 16, 2007

By:

  
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

Application Number		09787461
Filing Date		2001-03-02
First Named Inventor	Esteban Cvlikovich	
Art Unit	1614	
Examiner Name	Phyllis G. Spivack	
Attorney Docket Number	13566.105002	

## **U.S.PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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## **U.S.PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20060030571	A1	2006-02-09	Rinehart et al.	
	2	20070082856	A1	2007-04-12	Gianni et al.	
	3	20070128201	A1	2007-06-07	D'Incalci et al.	
	4	20060094687	A1	2006-04-04	Beijnen et al.	
	5	20070004691	A1	2007-01-04	Donald et al.	

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## **FOREIGN PATENT DOCUMENTS**

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Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup> j	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	WO 2005/049030	WO	A1	2005-06-02	Rowinsky et al.		<input type="checkbox"/>
	2	WO 2005/049031	WO	A1	2005-06-02	Rybak		<input type="checkbox"/>
	3	WO 2006/046080	WO	A1	2006-05-04	Gilles et al.		<input type="checkbox"/>
	4	WO 2002/36135	WO	A1	2002-05-10	Takahashi et al.		<input type="checkbox"/>
	5	WO 2000/69441	WO	A1	2000-11-23	Cvitkovich et al.		<input type="checkbox"/>
	6	WO 2006/035244	WO	A1	2006-04-06	Allavena et al.		<input type="checkbox"/>

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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	McMeekin, D.S. et al., "Final results of a phase II study of weekly trabectedin in second/third line ovarian carcinoma," Journal of Clinical Oncology, 2005 ASCO Annual Meeting Proceedings. Vol. 23, No. 16S, Part I of II (June 1 Supplement), Abstract No. 5011, May 13-17, 2005	<input type="checkbox"/>
	2	Twelves, C.J. et al., "Phase I clinical and pharmacokinetic (PK) study of ecteinascidin-743 (ET-743) given as a one hour infusion every 21 days," 1998 ASCO Annual Meeting Proceedings, Abstract No. 889, 1998	<input type="checkbox"/>

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3	Bowman, A. et al., "Phase I clinical and pharmacokinetic (PK) study of ecteinascidin-743 (ET-743) given as a one hour infusion every 21 days," Annals Oncology, Abstract 452, 1998	<input type="checkbox"/>
4	Hendriks, H.R. et al., "High antitumor activity of ET743 against human tumor xenografts from melanoma, non-small-cell lung and ovarian cancer," Annals of Oncology, vol. 10, pages 1233-1240, 1999	<input type="checkbox"/>
5	Michaelson, M.D. et al., "Phase II study of three hour, weekly infusion of trabectedin (ET-743) in men with metastatic, androgen-independent prostate carcinoma (AIPC)," Journal of Clinical Oncology, 2005 ASCO Annual Meeting Proceedings, Vol. 23, No. 16S, Part I of II (June 1 Supplement), Abstract No. 4517, May 13- 17, 2005	<input type="checkbox"/>
6	Taamma, A. et al., "Ecteinascidin-743 (ET-743) 24 hours continuous infusion (CI): clinical and pharmacokinetic phase I study in solid tumor patients (PTS). Preliminary Results" 1998 ASCO Annual Meeting Proceedings, Abstract No. 890, 1998	<input type="checkbox"/>
7	Villalona-Calero, M. et al., "A phase I and pharmacokinetic study of ET-743, a novel DNA minor groove binder of marine origin, administered as a 1-hour infusion daily x 5 days," Annals Oncology, Abstract 453, 1998	<input type="checkbox"/>
8	Ricofrio, M. et al., "Ecteinascidin-743 (ET-743) 24 hours continuous infusion (CI): Clinical and pharmacokinetic phase I study progressive report," 23rd European Society for Medical Oncology Congress, Abstract 639P, November 6-10, 1998	<input type="checkbox"/>
9	Ghielmini, M. et al., "In vitro schedule-dependency of myelotoxicity and cytotoxicity of Ecteinascidin 743 (ET-743)," Annals of Oncology, vol. 9, pages 989-993, 1998	<input type="checkbox"/>
10	Cvitkovich, E. et al., "Ecteinascidin-743 (ET-743) 24 hour continuous intravenous infusion (CI) phase I study in solid tumors (ST) patients," Annals Oncology, Abstract 456, 1998	<input type="checkbox"/>
11	Jimeno, J.M. et al., "Enhancing the preclinical in vivo antitumor activity of ecteinascidin 743, a marine natural product currently in phase II clinical trials," Proceedings of the 1999 AACR-NCI-EORTC International Conference, Clinical Cancer Research, Volume 5, Abstract No. 306, November 1999	<input type="checkbox"/>
12	Hillebrand, M.J.X. et al., "Pharmacokinetics of ecteinascidin-743 (ET-743) in three phase I studies," Annals Oncology, Abstract No. 455, 1998	<input type="checkbox"/>
13	Cvitkovich, E. et al., "Final results of a phase I study of ecteinascidin-743 (ET-743) 24 hour (h) continuous infusion (CI) in advanced solid tumors (AST) patients (pts)," 1999 ASCO Annual Meeting Proceedings, Abstract No. 690, 1998	<input type="checkbox"/>

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14	Forouzesh, B. et al., "Phase I and pharmacokinetic study of the marine-derived DNA minor groove binder ET- 743 on a weekly x3 every-4-week schedule in patients with advanced solid malignancies," Proceedings of the 2001 AACR-NCI-EORTC International Conference, Abstract No. 209, October 29-November 2, 2001	<input type="checkbox"/>
15	Ghielmini, M. et al., "Schedule-dependent myelotoxicity induced in vitro by the new marine derived minor groove interacting agent ecteinascidin 743," ECCO, vol. 9, Abstract No. 807, September 17, 1997	<input type="checkbox"/>
16	Taamma, A. et al., "Phase I clinical study of ecteinascidin-743 (ET-743) as a 24 hours continuous intravenous infusion (CI) in patients (pts) with solid tumors (st): A progress report," ECCO, vol. 9, Abstract No. 1119, September 18, 1997	<input type="checkbox"/>
17	Barrera, H. et al., "Interaction of ET-743 and standard cytotoxic agents against a panel of human tumor cell lines," Proceedings of the American Association for Cancer Research, Volume 40, page 591, Abstract No. 3896, March 1999	<input type="checkbox"/>
18	Fourouzesh, B. et al., "Phase I and pharmacokinetic study of ET-743, a minor groove DNA binder, administered weekly to patients with advanced cancer," Proc Am Soc Clin Oncol, vol 20, 2001 ASCO Annual Meeting Proceedings, Abstract No. 373, 2001	<input type="checkbox"/>
19	Garcia Gravalos, M.D., et al., "In vitro schedule-dependent cytotoxicity by ecteinascidin 743 (ET-743) against human tumor cells," 23rd European Society for Medical Oncology Congress, Abstract No. 652, November 6- 10, 1998	<input type="checkbox"/>
20	Hidalgo, M., et al., "A phase I and pharmacokinetic (PK) study of ET-743, a novel minor groove binder of marine origin administered on a daily x 5 schedule," 23rd European Society for Medical Oncology Congress, Abstract No. 613P, November 6-10, 1998	<input type="checkbox"/>
21	Drugs Fut., "Ecteinascidin-743" vol. 22, no. 11, page 1279, 1997	<input type="checkbox"/>
22	Forouzesh, B., et al., "Phase I and pharmacokinetic study of ET-743, a minor groove DNA binder, administered weekly to patients with advanced cancer," European Journal of Cancer, ECCO 11, volume 37, supplement 5, Abstract No. 106, October 21-25, 2001	<input type="checkbox"/>
23	Valoti, G., et al., "Ecteinascidin-743 (ET-743), a marine natural compound, shows antitumor activity against human ovarian carcinoma xenografts," European J. of Cancer, vol. 34(2), page S39, Abstract PP179, 1998	<input type="checkbox"/>
24	Jimeno, J. et al., "Phase I and pharmacokinetic (PK) study of Et-743, a novel minor groove binder of marine origin on a daily [times] 5 schedule," 1998 ASCO Annual Meeting Proceedings, Abstract No. 737, 1998	<input type="checkbox"/>

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25	Villalona-Calero, M. et al., "Final results of a Phase I and pharmacokinetic (PK) study of the marine minor groove binder ET-743 on a daily x 5 schedule," 1999 ASCO Annual Meeting Proceedings, Abstract No. 691, 1999	<input type="checkbox"/>
26	Gurtler, J.S. et al., "Trabectedin in third line breast cancer: a multicenter, randomized, phase II study comparing two administration regimens," Journal of Clinical Oncology, 2005 ASCO Annual Meeting Proceedings, vol. 23, no. 16S, part I of II (June 1 Supplement), Abstract No. 625, 2005	<input type="checkbox"/>
27	Twelves, C.J. et al., "Phase I and pharmacokinetic study of ecteinascidin-743 (ET-743) given as a one hour infusion every 21 days," ECCO, vol. 9, Abstract No. 1107, September 18, 1997	<input type="checkbox"/>
28	Izbicka, E. et al., "In vitro antitumor activity of the novel marine agent, Ecteinascidin-743 (ET-743, NSC- 648766) against human tumors explanted from patients," Annals of Oncology, vol. 9, pages 981-987, 1998	<input type="checkbox"/>

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**EXAMINER SIGNATURE**

Examiner Signature	Date Considered
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